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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,566	03/13/2002	Hiroshi Kayahara	216120US0PCT	8672
22850	7590	02/25/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			FLOOD, MICHELE C	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1654

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,566

Applicant(s)

KAYAHARA ET AL.

Examiner

Michele C. Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0203.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-3, on January 14, 2004 is acknowledged. The traversal is on the ground that unity of invention does exist between the groups, a technical relationship between them being present. This is not found persuasive for the reasons set forth in the previous Office action, and for the reasons set forth below. For instance, Applicant argues, "The Examiner has not explained why each group lacks unity with each other group and has not specifically described the unique special technical features in each group to justify the conclusion of lack of unity of invention". However, on page 3 through page 4, under item Number 2, the Office clearly states the reasons held for lack of unity in the instantly claimed inventions:

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims 1-6, 14 and 15, at least, are anticipated by or obvious over Saito et al., JP 10-77300 A, Saito et al., JP 9-40693 A, Saito et al., JP 9-37719 A, and Saito et al., Journal of Agricultural Food Chemistry (1997), 45: 720-724, because each of the cited patents and/or reference teach prolyl endopeptidase inhibiting activity in rice, and in maize, in soyabean, respectively, and the use thereof for treating disturbances of cerebral function. Therefore, they do not have a common technical feature over the prior art. With regard to Claim 13, the claim as drafted, does not necessarily *per se* relate to a compound having the claimed functional effect of prolyl endopeptidase inhibiting activity, wherein the compound is derived from a cereal grain extract. Moreover, Applicant has presented multiple inventions for prosecution on the merits. For instance, Applicant has claimed more than one product and claimed more than one method of using a product. Therefore, the claimed groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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Thus, contrary to Applicant's argument, the inventions listed as Groups I-IX do not have unity of invention because they do not share a common technical feature over the prior art as a whole, as evidenced by the cited patent and non-patent literature.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-3 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruyuma et al. (AX), Saito et al. (AY), Dziuba et al. (U), Saito et al. (AO), Saito et al. (AP), Saito et al. (AQ) and Miyoshi et al. (V).

Applicant claims a prolylendopeptidase-inhibitive agent, comprising an extract of a cereal grain as an active component. Applicant further claims a prolylendopeptidase-inhibitive agent according to Claim 1, wherein the cereal grain is a grain or seed of at least one member selected from the group consisting of rice plant, wheat, corn, soybean, milo, buckwheat, foxtail millet, barnyard grass, proso, and sesame.

Maruyuma teaches an extract of a maize endosperm and an extract of soybean comprising prolylendopeptidase inhibiting agents, and the use thereof for treatment of cerebral dysfunction. Saito (AY) teaches an extract of rice, e.g., sake cake and sake

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concentrate comprising a prolylendopeptidase-inhibitive agent, and the use thereof for treatment of cerebral dysfunction. Dziuba teaches extracts of barley, rice, sorghum and oat comprising prolylendopeptidase-inhibitive agents, in Table 4 on page 36. Saito (AO, JP 10077300 A) teaches an extract of rice comprising a prolylendopeptidase-inhibitive agent, and the use thereof for treatment of dementia. Saito (AP, JP 09040693) teaches an extract of rice, e.g., sake lees from brewed sake, prolylendopeptidase-inhibitive agent, and the use thereof for treatment of cerebral dysfunction. Saito (AQ, JP 09037719A) teaches an extract of brown rice, milled rice or a brewed cereal, e.g., sake and miso or soy sauce, prolylendopeptidase-inhibitive agent, and the use thereof for treatment of senile dementia. Miyoshi teaches an extract of corn comprising a prolylendopeptidase-inhibitive agent, on page 430, lines 3-5. Furthermore, Miyoshi suggests the use of a prolylendopeptidase-inhibitive agent as a therapeutic drug for the treatment of amnesia, on page 429, lines 9-13.

Each of the cited references set forth above anticipate the claimed subject matter.

Allowable Subject Matter

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (570) 272-0964. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood
MICHELE FLOOD
PATENT EXAMINER

MCF

February 18, 2004